

§ 493.905

certified specialty, subspecialty, and analyte or test within 60 days after the date by which the laboratory must report proficiency testing results to the proficiency testing program.

(2) Provide HHS with reports of PT results and scores of individual performance in cytology and provide copies of reports to participating individuals, and to all laboratories that employ the individuals, within 15 working days of the testing event;

(b) Furnish to HHS cumulative reports on an individual laboratory's performance and aggregate data on CLIA-certified laboratories for the purpose of establishing a system to make the proficiency testing program's results available, on a reasonable basis, upon request of any person, and include such explanatory information as may be appropriate to assist in the interpretation of the proficiency testing program's results;

(c) Provide HHS with additional information and data upon request and submit such information necessary for HHS to conduct an annual evaluation to determine whether the proficiency testing program continues to meet the requirements of §§ 493.901 through 493.959;

(d) Maintain records of laboratories' performance for a period of five years or such time as may be necessary for any legal proceedings; and

(e) Provide HHS with an annual report and, if needed, an interim report which identifies any previously unrecognized sources of variability in kits, instruments, methods, or PT samples, which adversely affect the programs' ability to evaluate laboratory performance.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.905 Nonapproved proficiency testing programs.

If a proficiency testing program is determined by HHS to fail to meet any criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program, CMS will notify the program and the program must notify all laboratories enrolled of the non-approval and the reasons for non-approval within 30 days of the notification.

42 CFR Ch. IV (10–1–14 Edition)

PROFICIENCY TESTING PROGRAMS BY SPECIALTY AND SUBSPECIALTY

§ 493.909 Microbiology.

The subspecialties under the specialty of microbiology for which a program may offer proficiency testing are bacteriology, mycobacteriology, mycology, parasitology and virology. Specific criteria for these subspecialties are found at §§ 493.911 through 493.919.

§ 493.911 Bacteriology.

(a) *Types of services offered by laboratories.* In bacteriology, for proficiency testing purposes, there are five types of laboratories:

(1) Those that interpret Gram stains or perform primary inoculation, or both; and refer cultures to another laboratory appropriately certified for the subspecialty of bacteriology for identification;

(2) Those that use direct antigen techniques to detect an organism and may also interpret Gram stains or perform primary inoculation, or perform any combination of these;

(3) Those that, in addition to interpreting Gram stains, performing primary inoculations, and using direct antigen tests, also isolate and identify aerobic bacteria from throat, urine, cervical, or urethral discharge specimens to the genus level and may also perform antimicrobial susceptibility tests on selected isolated microorganisms;

(4) Those that perform the services in paragraph (a)(3) of this section and also isolate and identify aerobic bacteria from any source to the species level and may also perform antimicrobial susceptibility tests; and

(5) Those that perform the services in paragraph (a)(4) of this section and also isolate and identify anaerobic bacteria from any source.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-